St. John Medical Center
PeaceHealth

September 26, 2007

Bart Eggen
Washington State Department of Health
101 Israel Road SE
Tumwater, WA 98501

Dear Mr. Eggen,

Thank you for the opportunity to provide comment on the recommendations issued for the provision of percutaneous coronary intervention (PCI). PeaceHealth – St. John Medical Center fully supports the approved body of legislation allowing hospitals like ours to efficaciously provide these services to the patients we serve in our community. There are more than 400 cardiac patients who enter our doors each year who may benefit from such services.

We were somewhat dismayed when we received recommendations by HMA as to the provision of these services across the State of Washington. Not only did they seem to raise the bar far beyond original recommendations proposed some two-years ago but it appears they want to draw back into question the legitimacy of the *approved* body of legislation itself. We are deeply disappointed in these statements as they reflect poorly on our elected officials who worked incredibly hard to pass this piece of legislation. Not to mention how this reflects on the citizens of the State of Washington who do not have immediate access to life saving cardiac services.

There are some specific recommendations we would like to comment on and questions we have for The Department with regard to HMA's recommendations.

Recommendations

1) **Elective PCI should not be performed in hospitals without on-site surgery.** The highest level (A) of investigation, well powered prospective randomized studies, has not yet been performed to fully confirm the safety and quality of performing elective PCI without on-site cardiac surgery. This lack of gold standard evidence has contributed to the reluctance of expert panels, professional societies, and governmental regulatory agencies to endorse and permit the provision of elective PCI in hospitals without on-site cardiac surgery. Until Level A studies have been completed and evaluated, it is not in the best interests of the health of the residents of Washington to allow elective PCI to be performed without on-site surgery.

   We believe the department should strike this recommendation from the official record as it is in direct opposition to legislation passed by our elected officials. This reflects poorly on their work and sends a mixed message to the citizens of Washington State. It is true that Evidence Level A does not exist at present for the provision of PCI but it does not exist for the more than 27 states now safely performing these procedures on a daily basis. All of the available PCI retrospective outcomes study evidence suggests a lack of need to perform these studies based on current rates of complication and mortality.

Circumstances under which elective PCI without on-site surgery could be allowed:

2) **The applicant hospital must objectively quantify and document that there exists a significant unmet need and diminished access to medically justified elective PCI services and how their program will address this need in order for the State of Washington to consider the initiation of an elective PCI program in a hospital without on-site cardiac surgery.** Programs that focus on the care of the underserved and uninsured may need to be provided with special consideration for developing new interventional cardiology programs.

   PeaceHealth – St. John Medical Center fully supports this recommendation and we believe this is the essence through which legislation was passed in support of Percutaneous Coronary Intervention (PCI) in communities where timely access to these services is diminished or non-existent.

3) **The applicant hospital must submit a detailed analysis of the impact that their new elective PCI program will have on the utilization and volume of PCI performance at other hospitals with established elective PCI programs that are currently providing this service to the same patient population.** The existing programs will have an opportunity to respond. New programs should not be allowed if they would reduce the volume of existing hospitals below minimum national and State volume standards.

   PeaceHealth – St. John Medical Center does not support this recommendation as it would be speculative to presume the impact without having direct access to data provided by said organization. As a prime example, St. John Medical Center currently sends the majority of its' PCI cases to four different hospitals, three of which are in Portland, Oregon. These decisions are based on a combination of primary access, provider and patient preference. How could the determination therefore be made on impact without accounting for these factors? If anything, these programs should file as 'affected parties' to the Certificate of Need based on the impact they think it will have on their program.

4) **New elective PCI programs must submit a detailed recruitment and staffing plan for qualified nurses, catheterization lab techs, and interventional cardiologists that does not jeopardize the continued functioning of existing elective PCI programs in the same service area.** Recruiting qualified staff and providing 24/7 emergency PCI coverage in proximate rural or micro-urban hospitals could be problematic and could jeopardize the sustainability of both existing and new programs.

   PeaceHealth – St. John Medical Center supports this recommendation but again we have concern as to how this would create jeopardy for one facility over another. Without performing extensive and exhaustive analysis of the recruitment, retention and staffing plans for each organization impacted. We believe that fair and completely justifiable arguments could be made by both sides without benefit of privileged and confidential information being made available to the applicant hospital. We suggest that as part of the normal course of the Certificate of Need process these organizations qualifying as "affected parties" demonstrate the impact to their program. Development of services should not be based on the

impact of another competitor. These competitive programs currently provide no service to the patients served by St. John Medical Center.

5) **Hospitals initiating new elective PCI programs without on-site cardiac surgery must apply and qualify for participation in a well powered, prospective randomized multiple site study, such as the currently in progress C-PORT E project, assessing the outcomes of elective PCI's performed in hospitals with and without on-site cardiac surgery as a prerequisite for approval.** Failure to qualify for participation in such study will result in the denial of the elective PCI application.

   PeaceHealth – St. John Medical Center supports prospective trials but we do not support this recommendation as a prerequisite for approval.

6) **The applicant hospital must submit a detailed analysis of the impact the new elective PCI services will have on the Cardiovascular Disease (Cardiology) and Interventional Cardiology Fellowship Training programs at the University of Washington.** The University will have an opportunity to respond. It is in the best interests of Washington and other surrounding States to protect the only Cardiology and Interventional Cardiology training programs in northwest USA.

   We feel it is incumbent upon the State of Washington, not the applicant to demonstrate the impact they may or may not have on a State funded program. If enacted, we also believe this should be a retroactive ruling that encompasses all facilities across the State of Washington.

7) **The applicant hospital must submit an objective plan to achieve minimum PCI volume standards >300 by the end of year two and optimal volumes >400 by year 3.** Inability to meet volume standards should result in a review of their CON approval.

   PeaceHealth – St. John Medical Center does not support this recommendation. These volume standards are not consistent with guidelines proposed by the American College of Cardiology (ACC), which states that sufficient minimum volume standards for institutions should be 200 cases per year. We fail to see the logic proposed by the consultants for raising this number to a higher level. Studies suggesting a higher level of volume achieving better results must be examined relative to the practice patterns of said participants over the course of the study.

   The consultants failed to mention the study cited in New York had profound affects on the provision of cardiac services. Outcomes for individual providers and facilities were published by name in local newspapers. Companion research papers following this study indicate that this in fact adversely affected providers, patients and the communities they served. Providers felt compelled to complete more cases on lower risk patients skewing results over the three-year time period of the study so as not to appear on the bottom of the list of cardiac care providers in the region. The results suggested over utilization at the low-risk end of the interventional cardiac care spectrum and under-utilization in higher risk cases depriving these patients of life sustaining treatment. They also failed to mention the State of New York was itself dismayed by the results as they believed this would reduce healthcare costs over time when in fact they rose during the period of the study.

We also believe that if enacted, this should be a retroactive ruling that encompasses all facilities across the State of Washington.

8) **The applicant hospital must have two functional and fully equipped cardiac catherization laboratories with all appropriate devices, optimal digital imaging systems, life sustaining apparati including IABP staffed by qualified, experienced nursing and technical staff with documented competencies in the treatment of acutely ill patients.** Two labs are needed to assure the availability of catheterization lab for an emergency PCI when an elective PCI is in process.

PeaceHealth – St. John Medical Center fully supports this recommendation.

9) **The applicant hospital's catheterization laboratory must be staffed by a qualified, trained team of technicians and nurses experienced in interventional labs and in the treatment of acutely patients with hemodynamic and electrical instability.** The nursing staff must have CCU experience and documented competencies in invasive monitoring, temporary pacemaker placement, and IABP management.

PeaceHealth – St. John Medical Center supports appropriately qualified and trained staff but we do not support this recommendation as written. This is not a current requirement of the Washington Administrative Code (WAC) and we believe, if enacted, that this should be a retroactive ruling encompassing all facilities across the State of Washington.

10) **The applicant hospital must have on staff experienced Interventional Cardiologists who meet the certification, lifetime and annual PCI volume experience, and national benchmark outcome standards.**

PeaceHealth – St. John Medical Center fully supports this recommendation.

11) **Hospitals without on-site cardiac surgery must implement and monitor rigorous patient and lesion selection guidelines.** High risk patients and patients with high risk lesions must be referred to a hospital for elective PCI. Low risk patients with low risk lesions are most appropriate for elective PCI in a hospital without on-site surgery. After two years of operation, institutions and operators whose risk-adjusted outcome statistics are equivalent or superior to risk adjusted national data registries may apply for expansion of their patient selection criteria to include low risk patients with high risk lesions.

PeaceHealth – St. John Medical Center fully supports this recommendation.

12) **PCI devices (rotational atherectomy, directional atherectomy, laser atherectomy, extractional thrombectomy) with higher risks for acute complications should not be used at hospitals without on-site surgery.** Patients in whom the use of these devices is anticipated are to be referred to a hospital with on-site surgery.

PeaceHealth – St. John Medical Center fully supports this recommendation.

13) **Applicant hospitals must be prepared and staffed to perform primary emergency PCI 24 hours per day, 7 days per week in addition to the scheduled elective PCIs.** Professional associations recommend the provision of primary and elective PCIs for a facility and cardiologist to maintain adequate skills and competency.

PeaceHealth – St. John Medical Center supports the concept of this recommendation but we believe any measurable increase in service is of benefit to patients. We believe, if enacted, that this should be a retroactive ruling encompassing all facilities across the State of Washington.

14) **The applicant hospital must have a signed written agreement with a hospital with on-site cardiac surgery and with cardiac surgeons stating that referred patients will be accepted based on their medical condition and that cardiac surgery will be available for emergency CABG 24 hours per day, 7 days per week and during the hours of elective PCI performance.** The cardiologist will communicate directly with the surgeon concerning all transfers and will assure that vital patient information including images and videos be transferred if not already sent electronically.

PeaceHealth – St. John Medical Center fully supports this recommendation.

15) **The applicant hospital must provide emergency transport or have a signed agreement with a vendor who will initiate transportation to the backup hospital within 20 minutes and can achieve a transfer from decision to transfer to arrival in OR of backup hospital in <90 and ideally in <60 minutes. The emergency transport staff is qualified, trained, ACLS certified and competent in use of monitoring equipment, the management of an IABP, and provision of life sustaining support in route. A minimum of two annual timed transportation drills will be performed and reported to the quality program.**

PeaceHealth – St. John Medical Center fully supports this recommendation. However, we would prefer to see the recommendation stated in terms of the total time it takes to achieve arrival at the higher level facility. Adding the component around initiation of decision to transfer is ambiguous and confuses the issue at hand.

16) **The applicant hospital will conduct ongoing quality improvement evaluation and analysis of the outcomes (success and complication rates) of elective PCIs, benchmarking, compliance with hospital and State guidelines for patients and lesion selection/exclusion and device utilization, reviews of patients transferred for emergency cardiac surgery, and formalized case reviews.** The surgeons at the backup hospital are to formally participate in the review of all elective PCIs transferred for cardiac surgery.

PeaceHealth – St. John Medical Center fully supports this recommendation and believe this should be a retroactive ruling to encompass all facilities across the State of Washington regardless of the presence of open-heart surgery.

17) **The applicant hospital's cardiac catheterization laboratory and PCI program will fully participate in a national percutaneous intervention data base such as the American College of Cardiology – National Cardiovascular Data Registry (ACC-**

NCDR). Failure to meet or exceed national benchmarks for two consecutive years will result in a review of the program's certification.

PeaceHealth – St. John Medical Center fully supports this recommendation. This should be a retroactive ruling encompassing all facilities across the State of Washington

18) **The State of Washington should formally consider the designating selected regional hospitals with on-site cardiac surgery as primary PCI "centers of excellence" (similar to centralized Level I Trauma Centers) to which patients with Acute Myocardial Infarction and Acute Coronary Syndromes would be directly transported bypassing other hospitals.** This designation could result in improved outcomes and would help to avoid the costly round-the-clock duplication of services and redundancy of interventional cardiologist and cardiac catheterization laboratory team coverage of emergency rooms in nearby hospitals for primary PCIs.

PeaceHealth – St. John Medical Center does not support this recommendation. This proposal does not take into account facilities that routinely refer patients out-of-state for higher levels of care. This will inevitably draw into question the capacity of all programs as to their ability to accept patients emergently or non-emergently. For instance, Southwest Washington Medical Center maintains the only open-heart approved program in our region and they are routinely unable to accept patients needing a higher level of care due to capacity.

Capacity in and of itself does not only refer to physical capacity to house patients but also the ability to have providers, staff, operating rooms, and/or cardiac catheterization laboratories at the ready to receive said patients. It is often for this reason that facilities are unable to accept patients from Longview. Likewise, we would like this recommendation to be tied to recommendation 15 to include arrival in the OR. We have received anecdotal evidence on a routine basis, which suggests that patients transferred to these "higher-level" facilities often have extended wait times for procedure initiation when transferred due to capacity of provider, staff, operating room, or catheterization lab availability.

We thank you for your consideration of these comments and hope that a sincere effort will be made to take them into account during the rule making process. We look forward to our next meeting where we can get down to the business of improving cardiac care for the citizens of Washington State.

Sincerely,

Scott R. Laubisch
PeaceHealth – St. John Medical Center

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